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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,346	11/18/2003	Ming Zheng	CL2221USNA	7632

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,346

Applicant(s)

ZHENG ET AL

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-13, drawn to a method for dispersing a population of carbon nanotubes, classified in class 434, subclass 174.
 - II. Claims 14-20, drawn to a method of immobilization carbon nanotubes, classified in class 435, subclass 283.1.
 - III. Claims 21-27, drawn to carbon nanotubes, classified in class 435, subclass 287.2.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related to Invention III as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process i.e. the nanotube-nucleic acid complex can be made by direct contact between the nanotubes and nucleic acids, not requiring the stabilized nucleic acid solution or nanotube dispersion of Invention I.

Inventions I and II are independent and distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation and different function. The method of Invention I operates by contacting carbon nanotubes and stabilized nucleic acids and the method functions to disperse the nanotubes. In contrast, the method of Invention II operates by

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providing nucleic acids and solid support with binding pair members, associating nanotubes with the nucleic acids and then contacting with the solid support and the method functions to provide immobilized carbon nanotubes.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as exemplified by their different classification, restriction for examination purposes as indicated is proper. Further, a search for the inventions of all groups would not be co-extensive because a search indicating the process is novel or non-obvious would not extend to a holding that the product itself is novel or non-obvious; similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the process is known or would have been obvious.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. During a telephone conversation with S. Neil Feltham on 16 March 2005 a provisional election was made with traverse to prosecute the invention of III, claims 21-27. Affirmation of

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this election must be made by applicant in replying to this Office action. Claims 1-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The claims are drawn to a complex comprising an “unfunctionalized carbon nanotube”. The specification provides no description or defining characteristics of the unfunctionalized nanotube. The term “unfunctionalized” appears to be a negative limitation whereby certain elements and/ or functionality is excluded. However, the specification provides no guidance as to what elements or function is excluded or included.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-27 are indefinite in Claim 21 for the recitation "unfunctionalized carbon nanotube" because the recitation appears to be a negative limitation excluding some elements from the complex or excluding some functional property. However, the claims do not define what elements or function is excluded; the specification does not provide any defining support; and the open claim language "comprising" encompasses any additional elements or functionality. Therefore, one of skill in the art would not be apprised of the meets and bounds of the instant claims.

Claim 22 is indefinite for the recitation "double stranded DNA, RNA and PNA" because it is unclear whether "double stranded" modifies DNA or further modifies the RNA and the PNA. It is suggested the claim be amended to clarify.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are drawn to a complex comprising an "unfunctionalized carbon nanotube".

As stated above, the claims do not define what elements or functionality is excluded; the

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specification does not provide any defining support; and the open claim language "comprising" encompasses any additional elements and/or function of the nanotube. Therefore, the claims are given their broadest reasonable interpretation in view of the specification to encompass the prior art as cited below.

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

10. Claims 21-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Williams et al (AIP Conf. Proc., 2002, 663: 444; cited on 1449 of 26 February 2004 and page 2 of the instant specification).

Regarding Claim 21, Williams et al disclose a nanotube complex comprising a nanotube bound to a nucleic acid (Abstract). The claimed nucleic acid is encompassed by the PNA of Williams because PNA comprises nucleic acids (see pages 2-3 of Williams). Furthermore, Williams hybridizes the nanotube complex with DNA thereby providing a complex comprising nanotubes and DNA (page 4 of Williams).

The instant claims are drawn to a complex comprising an unfunctionalized nanotube. As stated above, the open claim language "comprising" encompasses additional elements and functionality.

It is further noted that the nanotube complex of Williams comprises "unfunctionalized" nanotubes because absent the PNA, the nanotubes do not have hybridization functionality.

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Additionally, Williams derivatizes the nanotubes with PNA (page 2). To perform the derivatization, Williams first carboxylates the ends of the nanotubes, forms NHS esters and displaces the esters with PNA in the presence of "a large excess of PNA" (pages 2-3). The displacement results in PNA-nanotube binding. Hence, the reactive groups on the nanotubes are displaced (removed) to couple the PNA to the nanotube whereby the nanotubes are no longer functionalized. The resulting complex comprises unfunctionalized nanotubes and nucleic acids.

Regarding Claim 22, Williams et al disclose the complex wherein the nucleic acid is PNA (page 2) and via hybridization DNA (page 4).

Regarding Claim 23, Williams et al disclose the complex wherein the nucleic acid is synthetic i.e. PNA (page 2).

Regarding Claim 24, Williams et al disclose the complex wherein the nucleic acid is between 10 and 1000 bases (page 3, line 3).

Regarding Claim 25, Williams et al disclose the complex wherein the nucleic acid is functionalized with a member of a binding pair e.g. a base that hybridizes to its complement (page 4, first full paragraph).

11. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Lieber et al (U.S. Patent No. 6,159,742, issued 12 December 2000).

Regarding Claim 21, Lieber et al disclose a nanotube complex comprising a nanotube bound to a nucleic acid (Column 8, lines 47-54).

The instant claims are drawn to a complex comprising an unfunctionalized nanotube. As stated above, the open claim language "comprising" encompasses additional elements (e.g. linker) and functionality.

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It is further noted that the nanotube complex of Lieber et al comprises “unfunctionalized” nanotubes because absent biological functionality provided by the nucleic acid, the nanotubes do not have functionality.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (AIP Conf. Proc., 2002, 663: 444; cited on 1449 of 26 February 2004 and page 2 of the instant specification) in view of Navot et al (U.S. Patent No. 5,650, 277, issued 2 July 1997).

Regarding Claims 26 and 27, Williams et al disclose a nanotube complex comprising a nanotube bound to a nucleic acid whereby the complex is useful for hybridization assays (Abstract). Williams et al do not teach the nucleic acid is modified with a binding pair member e.g. biotin/avidin or metal as required in Claims 26 and 27, however these modification were well known in the art at the time the claimed invention was made as taught by Navot et al.

Navot et al teach a method of nucleic acid hybridization and they teach an important step prior to the hybridization is immobilization of the nucleic acid thereby maximizing the accessibility of reaction components to the nucleic acid (Column 15, lines 23-30). They further

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teach preferred methods include modifying the nucleic acids with biotin or with magnetic beads (metal) (Column 15, lines 1-30).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the nucleic acids of Williams by attaching biotin or magnetic bead for nucleic acid immobilization for the expected benefit of maximizing the accessibility of reaction components to the nucleic acid as taught by Navot et al (Column 15, lines 23-30).

14. Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieber et al (U.S. Patent No. 6,159,742, issued 12 December 2000) in view of Williams et al (AIP Conf. Proc., 2002, 663: 444; cited on 1449 of 26 February 2004 and page 2 of the instant specification).

Regarding Claims 21-25, Lieber et al disclose a nanotube complex comprising a nanotube bound to a nucleic acid (Column 8, lines 47-54). Lieber et al teach the complex comprises biological functionality e.g. nucleic acids, but they are silent regarding specific nucleic acids. However, the claimed DNA and synthetic PNA of 10-1000 bases were well known are used with carbon nanotubes as taught by Williams et al who teaches the bio-functionalized nanotubes unites the recognition power of DNA with the electronic properties of nanotubes (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the DNA and synthetic PNA of Williams to the bio-functional nanotubes of Lieber for the expected benefit of uniting the recognition power of DNA with the electronic properties of nanotubes as taught by Williams (Abstract).

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Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 21-23 and 25-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 and 19 of copending Application No. 10/716,347. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to carbon nanotube-nucleic acid complexes and differ only in the '347 complexes are defined by the process of making. However, both claim sets define the same product as defined by their structures. Therefore, the products are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
March 28, 2005